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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------------|
| 10/589,357 | 10/02/2006 | Tadashi Goino | U017569-3 | 8173 |
| 140 | 7590 | 08/17/2009 | | |
| LADAS & PARRY LLP 26 WEST 61ST STREET NEW YORK, NY 10023 | | | EXAMINER WINSTON, RANDALL O | |
| | | | ART UNIT 1655 | PAPER NUMBER |
| | | | MAIL DATE 08/17/2009 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/589,357

Applicant(s)

GOINO, TADASHI

Examiner

Randall Winston

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CIS-100)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 0806

DETAILED ACTION

. Election/Restrictions

Applicant's election of species of A) carpophore B) Basidiomyces Aphyllphorales Ganoderma ganodermseae and Basidiomyces Polyporaceae Coriolus and Basidiomyces Agaricales hymenochaetaceae C) ginseng in the reply filed on 05/26/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Readable claims 1-2 and 4-13 have been examined on the merits. Claim 3 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 and 4-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the terms "Basidiomyces Aphyllphorales Ganoderma ganodermseae" and "Basidiomyces Polyporaceae Coriolus" and "Basidiomyces Agaricales hymenochaetaceae." No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning of "Basidiomyces Aphyllphorales

Ganoderma ganodermseae" and "Basidiomyces Polyporaceae Coriolus" and "Basidiomyces Agricales hymenochaetaceae." There is no definition of "Basidiomyces Aphyllphorales Ganoderma ganodermseae" and "Basidiomyces Polyporaceae Coriolus" and "Basidiomyces Agricales hymenochaetaceae" in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention. Accordingly the metes and bounds of this phrase are not clearly delineated (e.g., It appears to Examiner by interpreting the specification (working examples etc) that for Basidiomyces Aphyllphorales Ganoderma ganodermseae, Applicant is apparently claiming the species *Ganoderma lucidum*. It appears to Examiner by interpreting the specification (working examples etc) that for Basidiomyces Polyporaceae Coriolus, Applicant is apparently claiming the species *Coriolus Versicolor*. It appears to Examiner by interpreting the specification (working examples etc) that for Basidiomyces Agricales hymenochaetaceae, Applicant is apparently claiming the species *Phellinus linteus*.)

All other claims depend directly from the rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 and 4-13 are rejected under 35 USC 103(a) for being unpatentable over Kouge et al (US 20040029955) in view of Son (Derwent ACC NO 2002-146031 and/or KR 200108366A, see abstract), Yuan (US 20020136785) and Goino (US 6746675).

Although very unclear as drafted, Applicant claims composition and/or method of preparation (i.e. at a claimed pH) comprising a hot water extract component of the carpophore (i.e. carpophore is the fruit body of the fungus) of the elected species of Basidiomycetes Aphyllphorales Ganoderma ganodermseae (i.e. It appears to Examiner by interpreting the specification (working examples etc) that for Basidiomycetes Aphyllphorales Ganoderma ganodermseae, Applicant is apparently claiming the species *Ganoderma lucidum*) and/or Basidiomycetes Polyporaceae Coriolus (i.e. It appears to Examiner by interpreting the specification (working examples etc) that for Basidiomycetes Polyporaceae Coriolus, Applicant is apparently claiming the species *Coriolus Versicolor*) and/or Basidiomycetes Agricales hymenochaetaceae (i.e. It appears to Examiner by interpreting the specification (working examples etc) that for Basidiomycetes Agricales hymenochaetaceae, Applicant is apparently claiming the species *Phellinus linteus*) and also included within the claimed composition and/or method is a hot water extract of a ginseng root is apparently claimed.

Kouge teaches a composition and/or method of preparation (i.e. at a pH) comprising a water extract component of the fruit bodies of either *Ganoderma lucidum* and/or *Coriolus Versicolor* and/or *Phenllinus linteus* to treat vascular related diseases such as malignant tumor or tumor growth inhibition of diabetic retinopathy etc (see, e.g.

entire document including abstract paragraph 0013, 0029 and examples). Kouge, however, does not expressly teach within its claimed composition and/or method of preparation a hot water extract of a ginseng root to treat vascular related diseases such as a malignant tumor or tumor growth inhibition or diabetic retinopathy etc..

Son beneficially teaches a hot water extract of a ginseng to treat vascular related diseases such as a malignant tumor (see, e.g. abstract).

Yuan also beneficially teaches a water extract of a ginseng root to treat vascular related diseases that causes diabetic retinopathy (see, e.g. entire document including abstract).

Goino also beneficially teaches a water extract of a ginseng root to treat vascular related diseases such as tumor growth inhibition (see, e.g. entire document including abstract and claims).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kouge's composition and/or method teachings to include the other active ingredient of ginseng as taught by Son, Yuan and Goino because combining the above references claimed active ingredients and/or teachings would create the overall claimed composition and/or method of preparation comprising the claimed active ingredients and/or the claimed active preparation steps to treat vascular related diseases such as a malignant tumor or tumor growth inhibition of diabetic retinopathy etc (please note that the instantly disclosed water fungus extract extracted in a similar water extraction method as the claimed invention's water extraction method would intrinsically contained the claimed oxidation-reduction potential of an aqueous

solution properties). Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose (treat vascular related diseases)." Furthermore, the adjustments of other conventional working conditions (i.e. the modification of pH and heating the fungus with water because hot water is well known to aid in obtaining claimed active ingredients from fungus), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/
Primary Examiner, Art Unit 1655